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(54) Heizung zur Erwärmung von medizinischen Flüssigkeiten

(57) Die Erfindung betrifft eine Heizung zur Erwärmung von medizinischen Flüssigkeiten mit einem die Flüssigkeit führenden Kanal, der eine mäanderförmige oder spiralförmige Kanalstruktur aufweist, und mit einem elektrischen Heizelement, bestehend aus einer auf einem Trägerelement aufgebrachten Heizleiterbahn, wobei das Heizelement zumindest mit einem Teil der Oberfläche des Kanals in Berührung steht. Um eine Heizung mit einem möglichst schnellen Ansprechen bei Schaltvorgängen zu schaffen, entspricht der Verlauf der Heizleiterbahn auf dem Trägerelement im wesentlichen dem der Kanalstruktur, wobei das Trägerelement eine geringe Wärmeleitfähigkeit aufweist.

DE 198 28 923 A 1

In-Line Heating

Patent Watch

Beschreibung

Die Erfindung betrifft eine Heizung zur Erwärmung von medizinischen Flüssigkeiten mit einem die Flüssigkeit führenden Kanal, der eine meanderförmige oder spiralförmige Kanalstruktur aufweist, und mit einem elektrischen Heizelement bestehend aus einer auf einem Trägerelement aufgebrachten Heizleiterbahn, wobei das Heizelement zumindest mit einem Teil der Oberfläche des Kanals in Berührung steht.

Eine derartige Heizung ist beispielsweise aus der WO 87/06140 für die Blutreinigung bekannt, um das gereinigte Blut vor der Zuführung in den Kreislauf des Patienten wieder auf Körpertemperatur zu erwärmen. Die Heizung besteht aus einem Beutel mit darin meanderförmig verschweißten Kanälen, der zwischen zwei Heizplatten eingebracht ist. Die Heizplatten bestehen ihrerseits jeweils aus einer Leiterplatte, auf der eine Leiterbahnstruktur aufgeätzt ist, die als Heizelement dient. Eine auf der Leiterplatte aufgebrachte Wärmeausgleichsschicht soll dabei für eine gleichmäßige Wärmeverteilung sorgen. Der Nachteil dieser Anordnung besteht im wesentlichen darin, daß diese aufwendig aufgebaut ist und daß aufgrund der großen Wärmekapazität der Heizplatte sich das Blut verhältnismäßig langsam erwärmt.

Aus der EP 0 012 123 A1 ist darüberhinaus eine Heizung zur Erwärmung von Blut bekannt, bei der ein meanderförmig geführter Schlauch zwischen zwei Heizplatten eingebracht ist. Die Heizplatten besitzen allerdings eine hohe Wärmekapazität, welche zu einer Erwärmung des umgebenden Gehäuses führt und zudem ein langsames Ansprechen der Heizung bedingt.

Aus der WO 97/09076 ist darüberhinaus eine Heizung zur Erwärmung von Blut bekannt, bei der das eine Durchflußkammer durchströmende Blut mittels elektromagnetischer Mikrowellenstrahlung aufgeheizt wird. Eine Wandung der Durchflußkammer besteht dabei aus einer Leiterplatte, auf der eine Mikrowellen-Antenne in Streifenleitungstechnik aufgebracht ist und die Mikrowellen in die Durchflußkammer abstrahlt. Ein Nachteil dieser Anordnung besteht darin, daß die Mikrowellen-Heizung eine verhältnismäßig aufwendige Schaltungstechnik bedingt und daß das Blut in der Durchflußkammer ungleichmäßig oder zu stark erwärmt werden kann. Außerdem ist eine zweite Kammer, die nicht von Flüssigkeit durchströmt wird, für die Einkopplung der Mikrowellen notwendig.

Eine weitere Möglichkeit einer Heizung zur Erwärmung von medizinischen Flüssigkeiten besteht darin, ein direkt beheizbares Edelstahlrohr zu verwenden. Diese Lösung kann allerdings nur durch ein aufwendiges Fertigungsverfahren verwirklicht werden.

Aufgabe der Erfindung ist es daher, eine kostengünstige Heizung zur Erwärmung von medizinischen Flüssigkeiten zu schaffen, die ein schnelles Ansprechen bei der Erwärmung des Blutes ermöglicht.

Diese Aufgabe wird durch die Merkmale des Patentanspruchs 1 gelöst. Die erfindungsgemäße Lösung besteht darin, daß der Verlauf der Heizleiterbahn auf dem Trägerelement im wesentlichen dem der Kanalstruktur. Auf diese Weise läßt sich auf der Größe einer Postkarte die erforderliche Leistung zur Flüssigkeitserwärmung, beispielsweise also bei der Blutreinigung, erreichen. Die direkte Beheizung der flüssigkeitsführenden Kanäle mit der Heizleiterbahn führen zu einem schnellen Ansprechen der Heizung, da zwischen den Kanälen zusätzliches Material nicht aufgeheizt werden muß. Da keine Metallplatte zur Wärmeübertragung notwendig ist, kann zudem eine Erwärmung des die Heizung umgebenden Gehäuses vermieden werden. Bei einer

Abschaltung der Heizung wird eine schnelle Abkühlung der Heilelemente realisiert, was insbesondere bei Fehlerzuständen vorteilhaft ist.

Ein besonders schnelles Ansprechen der Heizung kann erreicht werden, wenn die Materialien der Heizleiterbahn und des Trägerelementes jeweils so gewählt werden, daß das Heizelement eine möglichst geringe Wärmekapazität aufweist. Geht man davon aus, daß das Trägerelement eine Leiterplatte ist, auf der die Heizleiterbahn aufgebracht ist, dann besteht die Leiterplatte in üblicher Weise aus einer glasfaserverstärkten Kunststoffplatte und weist damit bereits die geforderten Materialeigenschaften auf. Die Wahl des Materials für die Heizleiterbahn hängt darüberhinaus von den Randbedingungen ab. Bei vorgegebener Schichtdicke und Streifenbreite der Heizleiterbahn bietet sich als Material Aluminium an, da dieses bei vorgegebenem Volumen eine besonders niedrige Wärmekapazität aufweist. Wird dagegen über eine bestimmte Länge der Heizleiterbahn ein bestimmter Widerstand zur Wärmeerzeugung gefordert, so läßt sich mit einer Kupfer- oder Silberbahn durch entsprechende Reduzierung der Schichtdicke eine besonders niedrige Wärmekapazität erreichen.

Ein besonders einfacher Aufbau der elektrischen Versorgung des Heizelements ergibt sich, wenn das Heizelement über einen Trenntrafo an die Netzspannung angeschlossen ist. Aufgrund der hohen Netzspannung bedingt dies allerdings dünne bzw. entsprechend lange Heizleiterbahnen, um einen hohen Widerstand des Heizelements zu erreichen. Außerdem muß eine Potentialtrennung im Fehlerfall gegenüber dem Patienten vorgesehen sein.

Eine andere Möglichkeit besteht darin, das Heizelement an ein elektronisch geregeltes Netzteil anzuschließen. Hierbei wird kein Trenntrafo benötigt, so daß das Netzteil besonders klein ausgeführt werden kann und an beliebige Netzspannungen anschließbar ist.

Zur Verwendung der Heizung für medizinische Zwecke ist es in der Regel erforderlich, daß der die Flüssigkeit führende Kanal als Einwegteil (sogenanntes Disposable) ausgeführt ist, um die Hygieneanforderungen für jede neue Anwendung erfüllen zu können. Hierbei sind grundsätzlich zwei Ausführungsformen denkbar. Zum einen kann der die Flüssigkeit führende Kanal als Einwegteil ausgeführt sein, während das elektrische Heizelement wiederverwendbar ist. Zum anderen kann aber auch die gesamte Heizung als Einwegteil ausgeführt sein, so daß die gesamte Heizung das sogenannte Disposable bildet.

Nach einer ersten Ausführungsform ist demnach vorgesehen, daß der Kanal in einem Plastikbeutel als Einwegteil verschweißt ist. An den Seiten des Plastikbeutels ist der mean- der- oder spiralförmig geführte Kanal zur Erwärmung durch ein Heizelement zugänglich, wobei der Plastikbeutel vorzugsweise zwischen zwei Platten verspannt ist, von denen zumindest eine Platte als elektrisches Heizelement ausgebildet ist. Die beiden Platten können schwenkbar miteinander verbunden sein, so daß der Plastikbeutel einfach zwischen die beiden Platten eingelegt werden kann. Besonders vorteilhaft ist es, wenn der Plastikbeutel an den Rändern mit Löchern versehen ist, die mit entsprechend an den Platten positionierten Zentrierstiften in Eingriff gebracht werden können, so daß die Kanalstruktur und der Verlauf der Heizleiterbahn zur Deckung kommen.

Nach einer zweiten Ausführungsform ist dagegen vorgesehen, daß der Kanal mit dem Heizelement unlösbar verbunden ist. Vorzugsweise weist hierbei der Kanal einen rechteckigen Querschnitt auf, so daß an einer Kante des Kanals eine Heizleiterbahn einfach aufgebracht werden kann. Es ist auch denkbar, daß die Heizleiterbahn in üblicher Weise auf einer Leiterplatte aufgebracht ist und das in einem weiteren Be-

schichtungsverfahren der die Flüssigkeit führende Kanal auf die Heizleiterbahn aufgeschichtet wird.

Weitere Einzelheiten und Vorteile der Erfindung werden anhand eines in der Zeichnung dargestellten Ausführungsbeispiels näher erläutert. In dieser zeigt:

Fig. 1 eine Draufsicht auf ein Einwegteil nach der ersten Ausführungsform,

Fig. 2 eine Draufsicht auf ein Heizelement nach der ersten Ausführungsform,

Fig. 3 einen Querschnitt durch ein Einwegteil mit einer integrierten Heizung nach der zweiten Ausführungsform und

Fig. 4 eine Messung des Ein- und Ausschaltvorgangs der erfindungsgemäßen Heizung im Vergleich zu einer herkömmlichen Heizung.

Fig. 1 zeigt die Draufsicht auf ein Einwegteil nach der ersten Ausführungsform. Das Einwegteil **10** umfaßt einen die Flüssigkeit führenden Kanal **11**, der in eine Folie eingeschweißt ist. An den Rändern **14** ist die Folie verstärkt und weist Löcher **15** auf, an denen das Einwegteil gegenüber dem Heizelement befestigt bzw. zentriert werden kann. An den Anschlüssen **12, 13** werden in üblicher Weise weiterführende Schläuche angeschlossen, wobei die Anschlüsse beispielsweise aus Luer-Konnektoren bestehen können.

Fig. 2 zeigt eine Draufsicht auf ein Heizelement nach der ersten Ausführungsform. Das Heizelement **20** besteht aus einer Leiterplatte **24**, auf der eine Heizleiterbahn **21** aufgebracht ist. Die Heizleiterbahn **21** weist dabei einen Verlauf auf, der im wesentlichen der Kanalstruktur des Einwegteils gemäß **Fig. 1** entspricht. Aus Vereinfachungsgründen ist die Heizleiterbahn an den Umkehrpunkten des meanderförmigen Verlaufs eckig ausgeführt, allerdings ist es selbstverständlich möglich, daß die Heizleiterbahn auch genau dem Verlauf des die Flüssigkeit führenden Kanals folgt. An den Anschlüssen **22, 23** ist eine schematisch dargestellte Spannungsquelle **26** angeschlossen, die die elektrische Energie liefert, die entlang der Heizleiterbahn **21** in Wärme umgewandelt wird. Auf der Leiterplatte **24** sind Zentrierstifte **25** vorgesehen, auf die das entsprechende Einwegteil mit den dafür vorgesehenen Löchern **15** aufgesteckt werden kann. Hierdurch ist sichergestellt, daß der Kanalverlauf **11** und der Verlauf der Heizleiterbahn **21** sich im wesentlichen decken. Auf das auf dem Heizelement aufgesetzte Einwegteil kann ein weiteres Heizelement aufgesetzt werden, so daß der in dem Einwegteil befindliche Kanal beidseitig beheizt wird. Alternativ kann vorgesehen sein, daß das Einwegteil mit einer weiteren Abschlußplatte mit dem Heizelement verspannt wird.

Die Heizleiterbahn besteht vorzugsweise aus Aluminium. Aluminium weist bei vorgegebenem Volumen eine besonders niedrige Wärmekapazität auf, so daß durch die Verwendung von Aluminium besonders hohe Schichtdicken erzielt werden können. Ebenfalls ist es denkbar, daß ein mitunter mehrere Millimeter dicker Aluminiumstreifen auf der Leiterplatte **24** verlegt wird. Beim Verspannen mit dem Einwegteil **10** drückt sich hierdurch die hervorstehende Aluminium-Heizleiterbahn in das Einwegteil bzw. den die Flüssigkeit führenden Kanal ein, so daß eine besonders große Berührungsfläche zwischen dem Kanal und der Heizleiterbahn hergestellt werden kann.

Fig. 3 zeigt einen Querschnitt durch ein Einwegteil mit einer integrierten Heizung nach der zweiten Ausführungsform. Die Ausgestaltung des elektrischen Heizelements gleicht damit der gemäß **Fig. 2**, so daß das elektrische Heizelement aus einer Leiterplatte **30** mit einer darauf meanderförmig verlegten Heizleiterbahn **31** besteht. Auf der Heizleiterbahn **31** ist der die Flüssigkeit führende Kanal **32** aufgesetzt und ist mit der Heizleiterbahn unlösbar verbunden.

Fig. 4 zeigt eine Messung des Ein- und Ausschaltvorgangs. Der Verlauf **40** zeigt den Temperaturverlauf der erfindungsgemäßen Heizung, der Verlauf **41** dagegen den Verlauf einer herkömmlichen Heizung, die aus einer Silikonheizleitermatte aufgebaut ist. Hierbei wurde 15°C kaltes Wasser mit einem Fluß von 125 ml/Minute und 160 Watt erwärmt. Nach 10 Minuten wurde die Heizung abgeschaltet. Es zeigt sich, daß die erfindungsgemäße Heizung wesentlich schneller auf Schaltvorgänge anspricht.

Die Rückseite des elektrischen Heizelementes wurde bei dem Versuch mit einer PVC-Platte abgedeckt, die nur handwarm wurde. Somit weist die erfindungsgemäße Heizung eine geringe Wärmeabfuhr auf und kann damit bei entsprechender Konstruktion in ein dafür vorgesehenes Gehäuse eingesetzt werden.

Für eine präzise Regelung ist eine zweistufige Ausführung der Heizleiterbahn denkbar. Durch eine entsprechende Verwirbelung der Flüssigkeit kann zudem eine gleichmäßige Temperaturverteilung erreicht werden.

Patentansprüche

1. Heizung zur Erwärmung von medizinischen Flüssigkeiten,
mit einem die Flüssigkeit führenden Kanal, der eine meanderförmige oder spiralförmige Kanalstruktur aufweist, und
mit einem elektrischen Heizelement bestehend aus einer auf einem Trägerelement aufgebrachten Heizleiterbahn, wobei das Heizelement zumindest mit einem Teil der Oberfläche des Kanals in Berührung steht,
dadurch gekennzeichnet,
daß der Verlauf der Heizleiterbahn auf dem Trägerelement im wesentlichen dem der Kanalstruktur entspricht

2. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach Anspruch 1, dadurch gekennzeichnet, daß die Heizleiterbahn aus einem Material besteht, mit dem eine möglichst geringe Wärmekapazität des gesamten Heizelements erzielt werden kann.

3. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach einem der Ansprüche 1 bis 2, dadurch gekennzeichnet, daß das Trägerelement aus einem Material besteht, mit dem eine möglichst geringe Wärmekapazität des gesamten Trägerelements erzielt werden kann.

4. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß das Trägerelement eine Leiterplatte ist, auf der die Heizleiterbahn aufgebracht ist.

5. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß das Heizelement über einen Trenntrafo an Netzspannung angeschlossen ist.

6. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß das Heizelement an ein elektronisch geregeltes Netzteil angeschlossen ist.

7. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß der Kanal in einem Plastikbeutel als Einwegteil verschweißt ist.

8. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach Anspruch 7, dadurch gekennzeichnet, daß der Plasikbeutel zwischen zwei Platten verspannt ist, wobei zumindest eine Platte als ein elektrisches Heizelement ausgebildet ist.

9. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach Anspruch 8, dadurch gekennzeichnet,

daß die beiden Platten schwenkbar miteinander verbunden sind.

10. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach einem der Ansprüche 7 bis 9, dadurch gekennzeichnet, daß der Plasikbeutel an den Rändern mit Löchern versehen ist, die mit entsprechend an dem Trägerelement positionierten Zentrierstiften derart in Eingriff gebracht werden, daß die Kanalstruktur und der Verlauf des elektrischen Heizelements zur Deckung kommen.

11. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß der Kanal mit dem Heizelement unlösbar verbunden ist.

12. Heizung zur Erwärmung von medizinischen Flüssigkeiten nach Anspruch 11, dadurch gekennzeichnet, daß der Kanal einen rechteckigen Querschnitt aufweist, und daß an mindestens einer Kante des Kanals eine Heizleiterbahn aufgebracht ist.

Hierzu 2 Seite(n) Zeichnungen

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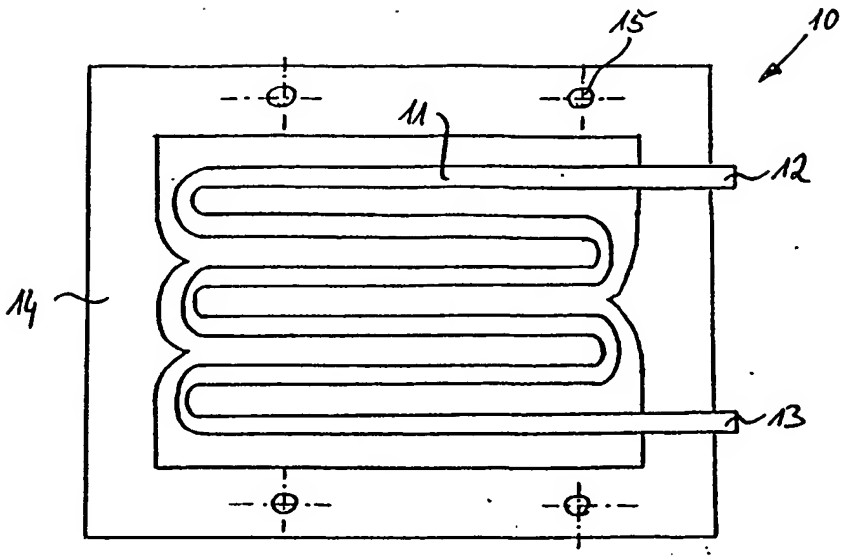

Fig. 1

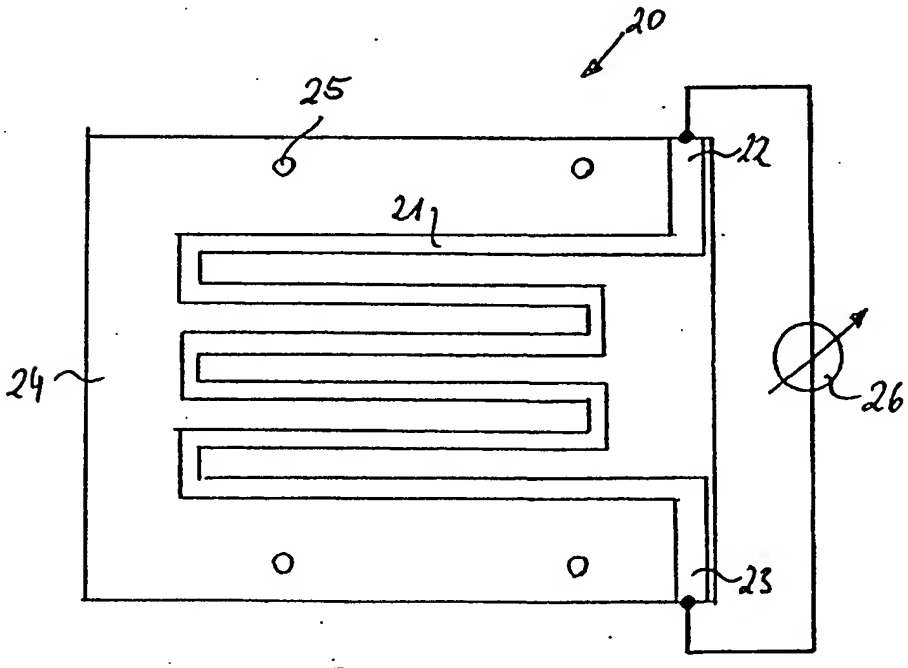

Fig. 2

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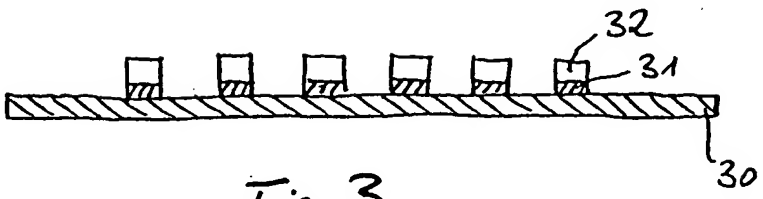

Fig. 3

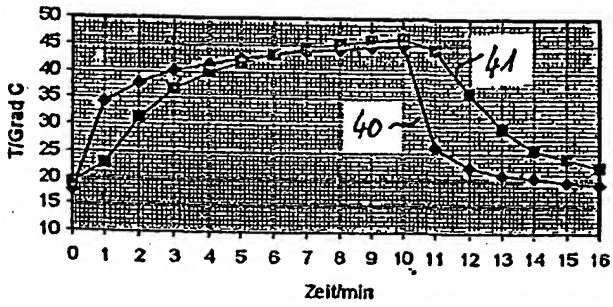

Fig. 4

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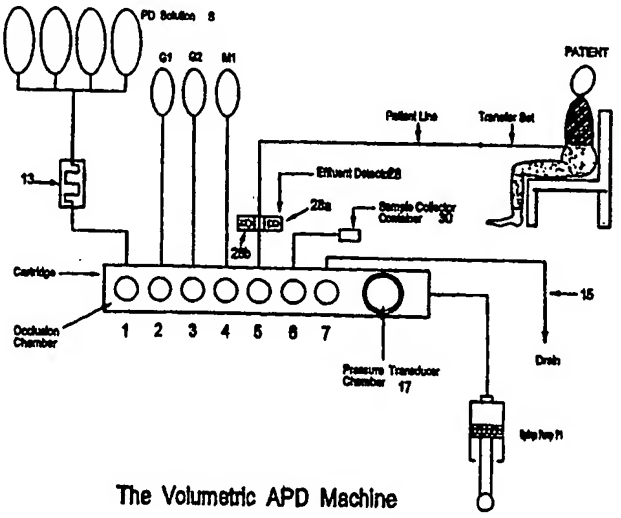
(54) Title: METHOD AND APPARATUS FOR PERFORMING PERITONEAL DIALYSIS



The Volumetric APD Machine

(57) Abstract

An automated peritoneal dialysis machine is provided which is capable of selecting and changing the composition of dialysate delivered to a patient (10) in the course of treatment to meet specific physiological needs. The apparatus includes means (P1) for metering solutions of osmotic agent, electrolytes and other desired dialysate components from separate solution containers (S1, S2) into mixing chamber means for combination in desired proportions. The means for delivery of fresh dialysis fluid to a patient (10) and for removing spent dialysis fluid from the patient includes means (17) for monitoring intraperitoneal pressure and other conditions of the fluid in the peritoneum and electronic control means responsible to the signal of monitoring means for controlling rates of dialysate infusion and removal.

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METHOD AND APPARATUS FOR PERFORMING PERITONEAL DIALYSIS

This invention relates to a new machine and method for carrying out automated peritoneal dialysis (PD).

Background of the Invention

Unlike the extracorporeal system used in hemodialysis (HD) to treat end stage renal disease (ESRD), PD makes use of the internal peritoneal membrane to purify the blood of ESRD patients. The two modalities for carrying out PD are automated peritoneal dialysis (APD) and the manual non-automated procedure of continuous ambulatory peritoneal dialysis (CAPD). According to the latter method, dialysis fluid is exchanged from four to six times throughout the day, every day. The fluid remains inside the patient for about four hours between exchanges and for a much longer period (10-12 hours) at night.

It has become conventional to refer to the basic stages of the PD procedure as FILL, DWELL and DRAIN. In the FILL stage, dialysate is instilled through a catheter into the peritoneal cavity of a patient.

During the fixed time period known as the DWELL, the dialysate draws soluble waste and excess fluid from blood contained in numerous blood vessels of the peritoneal membrane, by the operation of osmosis and diffusion. Additionally, the dialysate re-balances the electrolyte concentration and corrects for acidosis of the blood.

At the end of the DWELL, spent dialysate is removed from the peritoneal cavity (DRAIN) and discarded. This exchange action must be repeated several times over a twenty-four hour period, as the body continuously produces waste products.

Compared with HD, PD is a very gentle modality, its slow corrective action resembling that of the natural kidney. It is operationally simple, eliminates the need for venipunctures and has low operational costs. Because the system is not an extracorporeal one, there is no need for a high degree of heparinization, a factor which is especially important in the case of diabetic patients.

However, to date HD has continued to dominate in the treatment of ESRD patients. The following aspects of PD may be contributing factors to this state of affairs:

- In PD, the peritoneal membrane is exposed to the external environment every time a catheter is connected or disconnected from the solution supply, making infection (peritonitis) a significant problem.

- Currently available commercial dialysate for PD exhibits a low pH which is not truly compatible with the biochemistry of the peritoneal membrane. Consequently this bio-incompatibility is believed to be one of the factors which eventually degrades the performance of the membrane with time.

- The most popular osmotic agent used in PD dialysates is glucose, Glucose can be absorbed by the body via the peritoneum membrane. This can result in patient obesity and its accompanying complications.. Moreover, heat sterilization of the dialysate which contains glucose produces harmful glucose by-products.

- Current techniques of PD afford no ability to monitor the pressure build-up in the peritoneum during either Dwell or during the Fill sequence.

- Current PD solutions are of fixed composition and cannot be systematically adjusted either in their constituent parts or in the concentration of each constituent during a treatment.

In a continuing effort to provide adequate PD treatment for the varied population of ESRD patients, clinicians have developed a number of different forms of the APD modality of treatment. These include the APD modalities of:

(i) Continuous Cycling Peritoneal Dialysis (CCPD), a method of performing PD in which an automated cycler performs 4 to 6 regular exchanges every night.

(ii) Intermittent Peritoneal Dialysis (IPD), a method of performing PD in hospitals or at home with an automatic cycler two or three times a week for a period of about eight to twenty hours each time.

(iii) Nightly Peritoneal Dialysis (NPD), a method of performing nightly peritoneal dialysis at home for patients with high efficiency peritoneal membranes. Such patients do not fare well with long dialysate DWELL times.

(iv) Tidal Peritoneal Dialysis (TPD). This modality utilizes an initial maximum dialysate fill volume (usually three litres) and periodically, during a long and continuous DWELL time, drains a fraction of the fill volume (usually one-third, the tidal volume) and re-infuses about a similar amount, adjusting for ultrafiltration (excess fluid removed from the patient's body during kidney dialysis) into the patient.

A number of examples of more or less "automated" peritoneal dialysis machines are to be found in the art. Examples are afforded by U.S. Patent No. 4,096,859 (Agarwal et al.); U.S. Patent No. 5,141,492 (Dadson et al.); U.S. Patent No. 5,324,422 (Colleran et al.); and U.S. Patent No. 5,438,510 (Bryant et al.). These have proven to be unsatisfactory in various respects in addressing clinical concerns and in effectively implementing PD modalities such as those described above.

General Description of the Invention

Applicant's overall objective was to provide an automated peritoneal dialysis machine capable of fully "customizing" the composition of dialysate delivered to a patient to meet his or her immediate physiological needs and, to that same end, capable of monitoring the effectiveness of treatment during the treatment process and use this diagnostic information to optimise the customisation process.

It is a particular object of the invention to provide an automated peritoneal dialysis apparatus as aforesaid, including means for metering solutions of osmotic agent, electrolytes and other desired dialysate components from separate solution containers into mixing chamber means for combination, in desired proportions, to provide the desired dialysis fluid and for delivering a selected quantity of said dialysis fluid to the peritoneal cavity of a patient.

It is likewise an object of the present invention to provide automated peritoneal dialysis apparatus as aforesaid, wherein said means for metering dialysate components into the mixing chamber and delivering dialysis fluid to the patient includes means for withdrawing spent dialysis fluid from the patient.

It is a still further object of the invention to provide automated peritoneal dialysis apparatus as aforesaid, wherein the means for delivery of fresh dialysis fluid to a patient and for removing spent dialysis fluid from the patient includes means for monitoring interperitoneal pressure and electronic control means responsive to the signal of said pressure monitoring means, for controlling the rates of infusion of fluid into the patient and for the removal of fluid from the patient and, for the customisation of the dialysate.

Brief Description of the Drawings

Figure 1 is a schematic representation of the first "basic" APD machine according to the present invention.

Figure 2 schematically illustrates one of the liquid input/output ports and a portion of the occluding mechanism in the machine at Figure 1.

Figure 3 shows an exploded view of the occlusion mechanism for an automated peritoneal dialysis machine according to the present invention.

Figure 4 is a graphical representation of the variation of intraperitoneal pressure versus time during the cycles of an apparatus according to the present invention.

Figure 5 is a graphical representation of the volume of fluid removed to stabilize pressure as a function of time during the DWELL period of a dialysis cycle, as measured using APD apparatus according to the present invention.

Figure 6 is a schematic illustration of a second embodiment of APD machine according to the present invention.

Figure 7 is a schematic illustration of a second embodiment of APD machine according to the present invention.

Figure 8 is a preferred version of the apparatus embodiment of Figure 7, in which components are structurally integrated into a compact cartridge.

Figure 9 is a schematic illustration of a fourth embodiment of apparatus according to the present invention.

Detailed Description of the Invention

A "basic" layout of components of apparatus according to the present invention is illustrated schematically in Figure 1. The apparatus is connected to the peritoneal cavity of patient 10 by means of a patient tubing line 12, through which fresh fluid is infused and spent fluid is withdrawn.

An essential component of apparatus according to the present invention is an occlusion manifold 14, the hollow interior communication channel 16 of which is in communication with all of the fluid input lines to containers of selected dialysate solution components and to output tubing lines to the catheter and to drain.

In the arrangement shown in Figure 1, eight separate input or output connection ports into channel 16 of cartridge 14 are shown, numbered 1 to 8. Containers (solution bags) S_1, S_2 carry sterile PD solutions of two different electrolyte compositions and are connected to cartridge inputs 1 and 2 by tubing lines L_1 and L_2,

respectively. In-line heaters 13 are provided, as is conventional in PD apparatus, to warm the sterile PD solutions to body temperature. Containers S_1 and S_2 could alternatively carry standard PD solutions (glucose or similar as the osmotic agent).

Input 3 of manifold 14 is connected by line L_3 to a container G_1 of highly concentrated sterile osmotic agent (glucose solution or other known osmotic agent). Container bags M_1 and M_2 connected by lines L_4 and L_5, respectively, to the corresponding manifold inputs could contain different medications or additives to improve the clinical value of the solutions in S_1 and S_2. Apparatus according to the present invention includes a precise metering pump P_1 whose operation is described in more detail below. Aforementioned patient line 12 is connected to input 7, while a drain line 15 is connected to port 8.

For registering and monitoring the interperitoneal pressure from time to time during the course of treatment, a pressure transducer means 17 is preferably included, the signal from which is monitored by electronic control means for the apparatus (not shown).

A preferred arrangement for the occlusion mechanism of occlusion manifold 14 is illustrated in Figures 2 and 8. Figure 2 schematically illustrates one of the tubing connecting ports 18 onto which an input tubing line L fits. Port 18 communicates with interior communication channel 16 of occlusion manifold 14.

To ports 18 there correspond flexible sealing diaphragms 20, each positioned in the wall of manifold 14 opposite the wall through which corresponding port 18 enters channel 16, and electronically controlled plungers 22.

Figure 3 shows an exploded view an assembly of plungers 22 and 22c, springs 22a and 22b and motors 23 for assembly of an occlusion mechanism of the manifold of automated PD apparatus according to the present invention. In assembly, plungers 22 and plunger springs 22b are first inserted into manifold 14c. Cams 23a attached to individual small rotary motors 23 are inserted into the manifold, so that the plungers are retained inside the manifold by the cams and ride directly on the cams. The small springs 22a and corresponding plunger heads 22c are inserted from the top into respective plungers 22 through the manifold. All the motors 23 are mounted on a motor mounting plate 24. Two screws 24a are used to secure motor mounting plate 24 to manifold 14c.

Each motor 23 rotates its associated cam 23a and corresponding plunger 22c follows the cam for up or down movement. The respective up and down positions of the individual plungers 22 can be sensed electronically and a signal sent to the microprocessor means for stopping motors at up or down plunger positions as appropriate. The tubing connecting ports 18 terminating inside channel 16 of manifold 14 align with plungers 22c. The "up" position of a plunger has the effect of occluding the cartridge port to which it corresponds, while the "down" position opens the port. Fluid flows may accordingly be controlled as discussed below.

It is contemplated that the machine will be controlled by microprocessor means (not shown), having stored memory for on-line monitoring of information and for programming of set operational parameters. A removable memory card can also be incorporated to ensure easy collection and transfer of treatment data for the patients. Optionally, an interactive voice interface and visual and audio alarm systems can be incorporated to

simplify the diagnosis of problems during and after PD treatments.

The microprocessor means is programmed for receiving signals from various sensors and for producing output control signals for controlling the metering pump P1 and plungers 22 through an electromechanical means such as the motor/cam arrangement discussed above.

During dialysis, the desired filling fluid volumes of each cycle are programmed into the microprocessor. The ratios of the corresponding medications and/or additives are also entered. Initializing the machine operation, all input and output ports of the cartridge 14 are closed by their respective plungers. These plungers are controlled individually by their respective motors. When plunger 22c moves upwards (i.e., toward the manifold), it pushes against flexible diaphragm 20, closing the outlet of port tube 18 within channel 16 of the manifold, precluding entry or withdrawal of fluid from the chamber by way of that port. Moving the plunger downward leaves the tube outlet in communication with the chamber, so that fluid may flow freely in or out of the chamber and communicate with any other outlets which are also open at that time.

Referring specifically to Figure 1, the microprocessor electronic control means is programmed so that port #8 (to drain line 15) and port #6 (to the metering pump pumpline) are opened. In sequence, the plungers corresponding to input/output ports numbers 1, 2, 3, 4 and 5 are activated thus opening and closing input ports 1,2,3,4 and 5 at predetermined times. During the opening period, metering pump P1 operates to draw fluid in from respective container bags and to flush them out to the drain. Patient line 12 is flushed by opening either #1 or #2, opening #6 and drawing fluid out of

either S_1 or S_2, then closing #1 or #2, opening #7 and infusing the fluid into patient line 12.

For efficient operation in drawing calibrated volumes of fluid from container bags and infusing the withdrawn fluid to target locations, whether the container bags and the target locations are vertically above or below the machine, it is essential that metering pump P1 provide positive displacement of fluid and have a known volumetric displacement. One way this has been arranged in practice has been to have a variable volumetric displacement mechanism included in the metering pump P1. Variable displacement was achieved with controlled linear translation of a volume displacement member. This type of motion was achieved by coupling a worm gear to the output driveshaft of an electric motor. The controlled rotary motion of the electric motor is then smoothly translated into a controlled linear motion which in turn will adjust the volumetric displacement of the pump.

A common example of this type of metering pump is a syringe pump with controlled linear translation of the plunger in the barrel of the syringe. The linear motion (volume displacement) of a metering syringe pump was calibrated in the following manner. The internal shaft on the electric motor was digitally encoded. Its rotary position was optically sensed thus generating a set of electrical pulses whose number were directly proportional to linear displacement of the worm gear. One particular configuration which was used in this way gave a fluid displacement of 20cc for each 2.15 inches of linear travel of the worm gear. The lead screw of the worm gear had a lead of 0.12 inches and was driven through a gear box (gear ratio 81:1). The encoder of the motor produced 512 pulses/revolution. The microprocessor control means, through linkage to the motor shaft encoder, could track each pulse generated by the encoder. In principle this

metering system had a sensitivity of 30 x 10^{-9} litres. This is at least 3 orders of magnitude more precise than required for APD apparatus according to the invention to achieve its metering objectives. Naturally those skilled in the art could construct a number of variations of this particular device.

During FILL mode if solution S_1, say, is selected, ports numbers 1 and 6 would be opened and the metering pump activated to draw the correct amount of fluid from container bag S_1. That done, port #1 closes and desired additives G_1 selected by opening port #3, drawing the correct volume into P1, then closing port #3. Continuing in this way, incremental additions can be made of fluids from M_1 and M_2 into the pump. Then, to infuse the metered fluid composition into the patient, port #7 opens and the metering pump causes the fluid to be injected into the peritoneal cavity of the patient, while the machine monitors the volume of fluid instilled into the patient.

This injection procedure is repeated several times until the correct total amount of dialysis fluid has been delivered or some other predetermined state is achieved. A graphical example of such a predetermined state is shown in Fig 4 at point P_2. During the FILL mode, the intraperitoneal pressure will increase slowly from T_0 to T_1 and in proportion to the filled volume. There is an inflective increase in pressure at the maximum fill volume attained at time beyond T_1 and corresponding pressure P_2. The machine will be programmed to remove enough fluid to back off the pressure from the maximum P_2 to a safe and controlled pressure level P_1. This would be the steady state pressure for the monitoring process. The official DWELL period then begins at T_2.

Turning to the DWELL period, all ports of the manifold are closed and variations in the interperitoneal pressure are monitored by the microprocessor from signals

transmitted by in-line pressure transducer 17. Any ultrafiltration which occurs (drawing fluid from the body of the patient into the peritoneal cavity) will necessarily result in an increase in intraperitoneal pressure which, on detection, signals the control means to open ports #s 6 and 7. Pump P1 will then suck back sufficient fluid, namely, the excess amount, from the patient's peritoneal cavity until the steady state pressure level (P_1) has been restored. The volume which has been so removed during the DWELL period is recorded by the computer as "ultrafiltration" with respect to the time it was taken. Whenever the pressure reaches P_2, the pump is activated to reduce the fluid volume enough to drop the pressure back to the steady state P_1. This volume V_f is recorded with respect to time t_2 (the length will be dependent on osmotic pressure of the fluid). This action is operated as often as it may be necessary.

This process of restoring steady state pressure and recording the cumulative volume of fluid removed as a function of time in order to do so, is carried out automatically throughout the DWELL period and the measure of cumulative ultrafiltration (UF) is recorded. A graphical measurement of intraperitoneal pressure versus time affords valuable diagnostic information. When the pressure does not change from its steady state value for a predetermined period of time, it may be inferred that the dialysis fluid is no longer performing its optimal clinical function. At such a time, T_3 (Fig 4), the fluid can be safely drained out of the patient without waste of further time. An onset of a pressure drop, however, would indicate that the patient is absorbing fluid from the peritoneal cavity which could indicate that the patient is absorbing glucose from the dialysate, or that dialysate is leaking into extra-abdominal tissues. These undesirable clinical conditions are avoided by arranging the control logic of the machine to automatically drain

out all spent dialysate volume from the patient when such pressure drop occurs.

During the DRAIN mode ports #6 and #7 are opened. The metering pump P1 draws the spent fluid from the patient and into the syringe. This volume is measured as it is being withdrawn. When the syringe is full, port #7 closes and port #8 opens. The pump P1 reverses its direction and pushes the waste fluid from the syringe through the drain line and into a receptacle for spent dialysate. This is operated until all the fluid is drained out or the pressure registers negative, or until the end of the set DRAIN time. The final UF is then determined by the machine.

This completes one dialysis cycle. The above procedure is repeated as many times as required until the desired amount of treatment is obtained.

Another important characteristic of this invention is its ability to make decisions based on real-time physiological needs of a patient or provide previously unattainable clinical information. A graphical representation of the on-line monitoring of volume of fluid removed in order to stabilize pressure at a steady state, as a function of time during the DWELL period of one dialysis cycle, is provided in Figure 5 and is but one such example of new clinical information. The invention will allow the normal set DWELL time (T_2 to T_3) to be rationally adjusted. At maximum UF volume, V_m, the dialysis fluid has reached equilibrium with the plasma in the peritoneal membrane. Therefore anytime beyond T_x, would be treatment time wasted. A clinician could either program the machine to automatically drain the patient of the spent fluid and introduce fresh fluid for better dialysis or use the information to set more effective DWELL time for the next treatment. Alternatively if the set DWELL time terminates at the rising phase of the

ultrafiltration curve, then the dialysate is not being utilized properly. These are examples of the ability of the apparatus to automatically make decisions based on real-time physiological needs of a patient. This graph also reflects real time solute and fluid transport rates of the peritoneal membrane for any given dialysate formulation. That is, the greater the efficiency of the peritoneal membrane the greater the initial slope of the ultrafiltration curve and or the faster time T_x is achieved. For the first time clinicians will be able to quantify the transport characteristics of the membrane on-line and use this information to directly control the machine or allow the machine to make the necessary adjustments automatically.

A further example of the capability of apparatus according to the invention in providing previously unattainable clinical information and/or intelligent use of such information by the APD machine is as follows: In clinical PD applications, the characteristics of the peritoneal membrane with respect to its active surface area, and permeability (solute and fluid transport) are all variable and mostly unknown for any given patient. Hence methods have been developed to quantify peritoneal membrane performance. However, these methods are complex, indirect and none of them are on-line analytical procedures. Two methods used for assessing membrane performance are (a) the peritoneal Membrane Mass Transfer Area Coefficient (MTAC) and (b) the Peritoneal Equilibration Test (PET). . The later (PET), determines the ratio of dialysate-to-plasma (D/P) of a given solute and is the one most commonly used to assess patients. At best this is performed once a month. Currently it is impossible to obtain data to perform PET at various stages of the DWELL period during treatment. If this time dependent data could be obtained it could lead to a better clinical understanding of the different types of ultrafiltration failures. Combining the unique ability

of apparatus according to the present invention to secure a sample of the fluid during DWELL at known correlated points on the ultrafiltration curve clinicians will be better able to properly evaluate the PD treatment in vivo. This represents a major advance in the art of PD treatment. A related clinical advantage is that clinicians will immediately be able to correlate changes in ultrafiltration curve with the type of medication or additive used during a treatment cycle.

It will be appreciated from the foregoing that the pressure monitoring activities used to control the UF using a machine according to the present invention makes it possible to perform a true tidal peritoneal dialysis. By maintaining the pressure at its initial fill pressure P_1 we can infer that the actual volume of fluid in the cavity is the same as the initial fill volume. This volume is known. For the first time an APD machine will be able to use the actual volume of fluid in the peritoneal cavity and not a pre-estimated amount to determine the actual tidal withdrawal and refill volumes. This is a major improvement in the art.

Moreover, additional detectors and sensors may be included in the system and their signals taken into account to a programme microprocessor or diagnostic and therapeutic advantage. For example, a turbidimeter including a light source and light detector monitoring the clarity of the effluent during DRAIN can give early detection of the onset of infection. If patient line 12 is passed between such a light source and light detector, it will be possible to detect whether or not the patient's effluent is cloudy during DRAIN, owing to an onset of peritonitis (production of enhanced level of light-scattering white blood cells brought about by infection). The detector will transmit this information to the microprocessor and audio and visual alarms may be initiated, the machine triggered to empty metering pump

P1 and a sample of cloudy effluent collected for further analysis.

The machine could therefore be programmed to make important decisions as to the infusion pattern on the basis of signals from sensors reflecting the composition and pressure of fluid in the peritoneal cavity.

Alternative Embodiments of Apparatus

Although the "basic" machine shown in Figure 1 employs a metering pump to draw and deliver the apportioned dialysate components, the arrangement could be used without a metering pump at all, but employing a weighing system and gravity for the discharge of sterile fluids and medications from container bags supported vertically above the patient, with a weigh bag located below the patient for determining the volume.

Equally as valid, although the basic machine is designed to customize the dialysate from a plurality of solution bags, the machine can be used in a non customisation mode, i.e., with dialysate pre-mixed in each of one or more container bags. Each port can be connected to a dialysate of fixed formulation. The described diagnostic power of the apparatus can then be used to select which port is connected to the patient line (12) to FILL the patient, determine the DWELL period, and drain the patient of that selected formulation using the metering pump.

A second embodiment of a PD apparatus according to the present invention is illustrated schematically in Figure 6. The same reference numerals are used in Figure 6 and in the below-discussed Figures 7 and 8 to identify parts of the apparatus which are entirely analogous and co-functional with like-numbered components of the basic machine shown in Figure 1.

The second preferred embodiment as shown in Fig 6. depends on pump P1 for achieving compact arrangement and ease of clinical use and uniqueness in portability. The cartridge is divided into two distinct chambers 14a and 14b. The first chamber houses ports #1, #2, #3, #4, and #5. The second chamber houses ports #6, #7, and #8. The ports #4 and #7 are now connected to the metering pump P1 via one way valves V_1 and V_2 for fluid inflow and outflow respectively. The bulk sterile neutral fluid S (no osmotic agent), is connected to port #1 through heater 13. The osmotic agent G_1 (i.e. glucose etc.) is at port #2, and the medication M_1 is at #3. The inflow to the patient is at port #6 and the outflow from the patient is at port #5. Port #5 and #6 are joined to the patient line via the pressure transducer means 17.

In operation all the ports are initially closed. During FILL mode #1, #4, #6, and #7 are opened. The fresh fluid is drawn in by P1 from S through the heater, through the valve V_1. At a predetermined volume #1 closes, #2 opens and the correct amount of the osmotic fluid is also drawn into the metering pump. The port #2 then closes and #3 opens to allow the withdrawal of the desired volume of the medication M_1 into P_1. Then #3 is closed. Reversing direction the contents of P1 is discharged into the patient via V_2, pressure transducer 17 and the patient line 12. The above procedure is repeated several times until the correct dosage volume is delivered to the patient. By having unidirectional valves V_1 and V_2, the frequency of closing and opening of ports #4, #5, #6, and #7 is reduced.

During DRAIN mode only plungers #4, #5, #7, and #8 are opened. The spent fluid from the patient is drawn into P1 through the patient line, the pressure transducer 17, through #5, #4 and Valve V_1. The syringe P1 measures the drawn in fluid accordingly. The fe dback of the

pressure transducer regulates the rate of fluid drawn in by P_1 from the patient. When full, P1 is emptied through V_2, plungers #7 and #8 to the final drain. All the previously mentioned activities are equally applicable to this version. Plungers #4 and #7 are not strictly necessary, because, with plungers #s 1, 2, 3, 5, 6 and 8 all closed, the metering pump is isolated and there is no movement of fluid.

A machine according to this second embodiment could be operated from a normal table top or a short stand, with the solutions and medications located conveniently below the main machine. The machine could even be operated at the floor level. The positive displacement pump P1 ensures that the efficiency of the delivery system does not depend upon the relative vertical positions of the solutions, the patients and/or the final drain, as is the case in gravity-fed cyclers. This therefore makes the new machine universal for patients on normal beds, hospital beds or lying on floor mats.

A third preferred version is as shown in Figure 7. The component arrangements are similar to the first version shown in Figure 1 (the Basic Machine), discussed above. The sterile PD solution (electrolytes only) is at port #1. The Osmotic agents (G_1 , G_2) are at ports #2 and #3. The medication M_1 , is at port #4. The Patient line 12 is controlled by port #5. And port #6 controls the drain line 15. The metering pump P1 communicates directly with the whole occlusion chamber. And the fluid flowing in and out of metering pump P1 passes through a pressure transducer chamber 17' that communicates with pressure transducer 17. All the tubing lines communicate with occlusion manifold 14. Pressure in the lines, and hence in connected bags, or in the patient and in the drain line are all monitored by opening the appropriate port. Using this arrangement, the pressure readings could be used to detect other important conditions in addition to

all those already discussed under the previous versions; the detection of these, (a) empty solution bags (S, G_1, G_2 & M_1) (b) obstructions in the drain line and (c) obstructions in the patient line.

A "compact cartridge" version of the system of Figure 7 is as shown in Figure 8. The occlusion block 14, the heater and metering pump P1 are all integrated into a single compact cartridge. The heating chamber is divided into two sections: the initial heater chamber 13a that houses the incoming cold solution, and the corrugated heater section 13b that directs the fluid path to ensure proper heating of the solution. The output of the heater is attached to port #1.

A preferred embodiment of the new APD apparatus is as shown in Figure 9. The operation of this embodiment is the same as the one discussed above for the third version in Figure 7, except in this embodiment there are two additions, namely (a) effluent detector 28 and (b) sample collector port (at #6). The drain line 15 is now located at port #7.

The effluent detector comprises of a light source 28a facing a light detector 28b. Variations in the light intensities are detected by the light detector and the signals transmitted to microprocessor for the appropriate actions.

The patient line 12 passes between the light source 28a and the light detector 28b of the effluent detector 28. Hence during DRAIN if the patient's effluent is cloudy (due to an onset of peritonitis; infection-production of white blood cells), the light beam to the light detector is diffused. The detector transmits the message accordingly to the microprocessor. Both audio and visual alarms are initiated. When this happens the machine automatically, at the point of emptying the

metering pump P1, opens port #6 and sends a sample of the cloudy effluent solution into the sample collector container 30 (which could be a bag or a syringe). Then port #6 will be closed and the normal drain procedure will be continued by operating port #7.

If the apparatus had been set up to initiate peritonitis treatment, rapid peritoneum flush or flushes (fills immediately followed by drains), will be carried out. Then followed by treatment fill volumes containing medication or medications, automatically metered from the medication containers such as M_1, by the metering pump P1.

The effluent detector, similarly, will detect excessive amount of blood in the effluent (usually with new catheter operations or with new catheter break-ins), and could be programmed to automatically reduce the amount of heparin additive and or reduce the dialysate infusion volumes.

While particular embodiments of this invention have been described in relation to the accompanying drawings, it will be evident to those skilled in the art that changes and modifications may be made therein, without departure from the spirit of the invention as defined in the appended claims.

I CLAIM:

1. Apparatus for carrying out peritoneal dialysis on a patient whose peritoneal cavity is in communication with at least one patient catheter, said apparatus comprising:

(a) a manifold comprising a plurality of liquid input/output ports;

(b) occlusion means for selectively sealing off and re-opening communication between any one or more of said input/output ports and the other ports of the manifold;

(c) metering means in communication with at least a first one of said input/output ports, operable to withdraw and measure the volume of selected quantities of liquid from said manifold;

(d) a mixing chamber in communication with the manifold;

(e) a patient conduit line for connecting at least a second one of said input/output ports to said patient catheter;

(f) conduit lines for connecting others of said input/output ports to respective container bags of dialysate solution components; and

(g) means for controlling said occlusion means and said metering means, whereby a selected volume of each of selected ones of said dialysate components is withdrawn by said metering means to provide a dialysis solution in said mixing chamber of a desired final formulation.

2. Apparatus according to claim 1, wherein said means for controlling said occlusion means and said metering means consists of electronic control and sequencing means, operable to cause a selected volume of said final formulation dialysis solution to be injected through said patient conduit line into the peritoneal cavity line of the patient in a FILL phase and, after a first selected

time in a DWELL phase, to be withdrawn from the peritoneal cavity into said metering means.

3. Apparatus according to claim 1 or claim 2, further comprising a drain conduit line for connecting a third one of said input/output ports to a receptacle for spent dialysate, said electronic control and sequencing means being operable in a DRAIN phase following said first selected time to cause all or part of the spent dialysis solution withdrawn into said metering means to be injected through said drain conduit line into said receptacle.

4. Apparatus according to any one of claims 1 to 3, wherein said metering means comprises fluid transfer means including a pumping mechanism and reservoir means of calibrated variable volume, and electromechanical drive means operable to vary the volume of said reservoir means in a program of stepped increases or decreases of said calibrated volume in response to control signals from said electronic control and sequencing means.

5. Apparatus according to claim 4, wherein said metering means comprises a syringe pump having a syringe plunger and electromechanical drive means for stepped advancement or retraction of said syringe plunger in response to control signals from said electronic control and sequencing means.

6. Apparatus according to any one of claims 3 to 5, further comprising means for monitoring the intraperitoneal pressure of the patient and producing a first monitoring signal to said electronic control and sequencing means for use in determining and implementing operation steps of the apparatus appropriate to desired therapeutic treatment of the patient.

7. Apparatus according to any one of claims 3 to 6, further comprising electro-optical means for producing a second monitoring signal to said electronic control and sequencing means, said second monitoring signal being indicative of the turbidity of fluid in said patient conduit line at a selected time, for use in determining and implementing operations of the apparatus appropriate to desired therapeutic treatment of the patient.

8. A method for carrying out peritoneal dialysis on a patient whose peritoneal cavity is in communication with at least one patient catheter, said method comprising the step of maintaining the liquid pressure in the peritoneal cavity at a selected value, by removing excess liquid from, or injecting additional dialysate solution into the peritoneal cavity, in response to changes in the peritoneal pressure.

9. A method for carrying out peritoneal dialysis on a patient whose peritoneal cavity communicates with at least one patient catheter, the method comprising the steps of:

(a) providing an apparatus which includes

a manifold with a plurality of liquid input/output ports,

occlusion means for selectively sealing off and re-opening communication between any one or more of said input/output ports and the other ports of said manifold,

metering means in communication with at least a first one of said input/output ports, operable to withdraw and measure the volume of selected quantities of liquid from said manifold and to inject selected volumes of liquid into said manifold,

means for injecting selected volumes of liquid from said manifold into a mixing chamber;

a patient conduit line for connecting at least a second one of said input/output ports to said patient catheter, and

conduit lines for connecting others of said input/output ports to respective container bags of dialysate solution components;

(b) using electronic control and sequencing means, operable to control operation of said occlusion means and metering means, in conjunction with sensor means operable to convey monitoring signals to said electronic control and sequencing means indicative of the condition of liquid in the peritoneal cavity of the patient, in an automatic mode in which said control and sequencing means causes

(i) a selected volume of each of selected ones of said dialysate solution components to be withdrawn by said metering means to provide a dialysis solution in said mixing chamber of any desired final composition or formulation,

(ii) a selected volume of said dialysis solution to be subsequently injected through said patient conduit into the peritoneal cavity in a FILL phase and,

(iii) after a selected dwell time during a DWELL phase at least a portion of spent dialysis solution to be withdrawn from the peritoneal cavity into said metering means.

10. A method according to claim 9, wherein said selected dwell time is determined on the basis of monitoring signals received by said electronic control and sequencing means.

11. A method according to claim 9 or claim 10, wherein said apparatus provided to carry out the method further includes a drain conduit line for connecting a third one of said input/output ports to a receptacle for spent dialysate, and wherein said electronic control and sequencing means is used in a DRAIN phase following said first selected time to cause the apparatus to withdraw all or part of the spent dialysis solution into said

metering means and to be injected through said drain conduit line into said receptacle.

12. A method according to claim 11, wherein said sensor means comprises pressure transducer means operable to produce a monitoring signal indicative of the intraperitoneal pressure in the patient.

13. A method according to claim 11 or claim 12, wherein said sensor means comprises electro-optical means for producing a monitor signal indicative of the turbidity of fluid in said patient conduit line.

14. A method according to claim 12, wherein said automatic mode of operation includes maintaining the liquid pressure in the peritoneal cavity at a selected value by causing the apparatus to remove excess solution from, or inject additional dialysate solution into the peritoneal cavity, in response to the monitoring signals from said pressure transducer means.

15. A method according to claim 14, further comprising the step of measuring as a function of time the volumes of solution withdrawn from the peritoneal cavity of the patient to maintain substantially constant intraperitoneal pressure to characterize transport characteristics of the peritoneal membrane of the patient being treated.

16. A method according to any one of claims 9 to 15, wherein during said DWELL phase, a selected quantity of dialysis fluid is withdrawn from the peritoneal cavity and returned to the peritoneal cavity a selected number of times in order to agitate and homogenize the fluid.

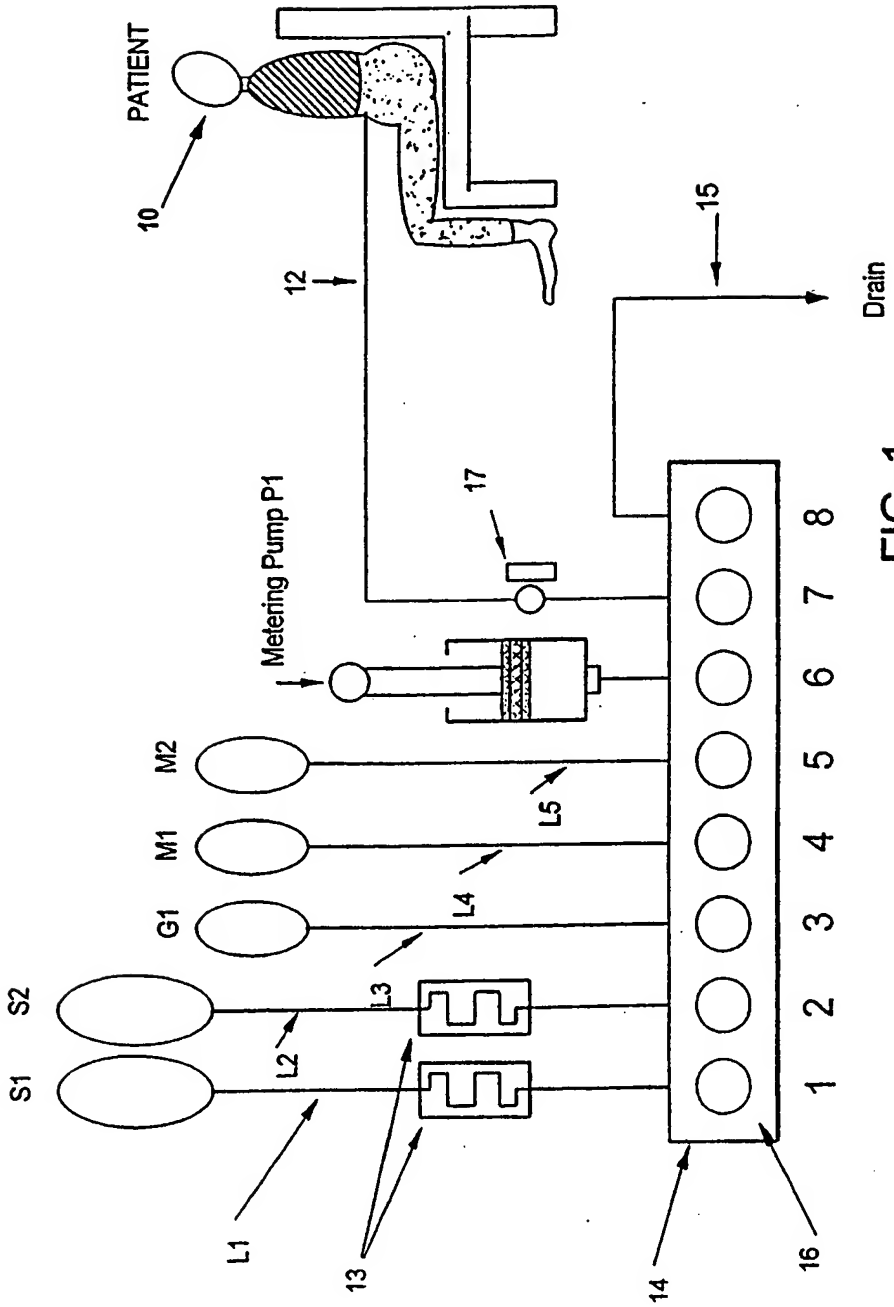
PATIENT
10
12
15
Drain
17
Metering Pump P1
M2
M1
G1
S2
S1
L1
L2
L3
L4
L5
13
14
16
1 2 3 4 5 6 7 8

FIG. 1

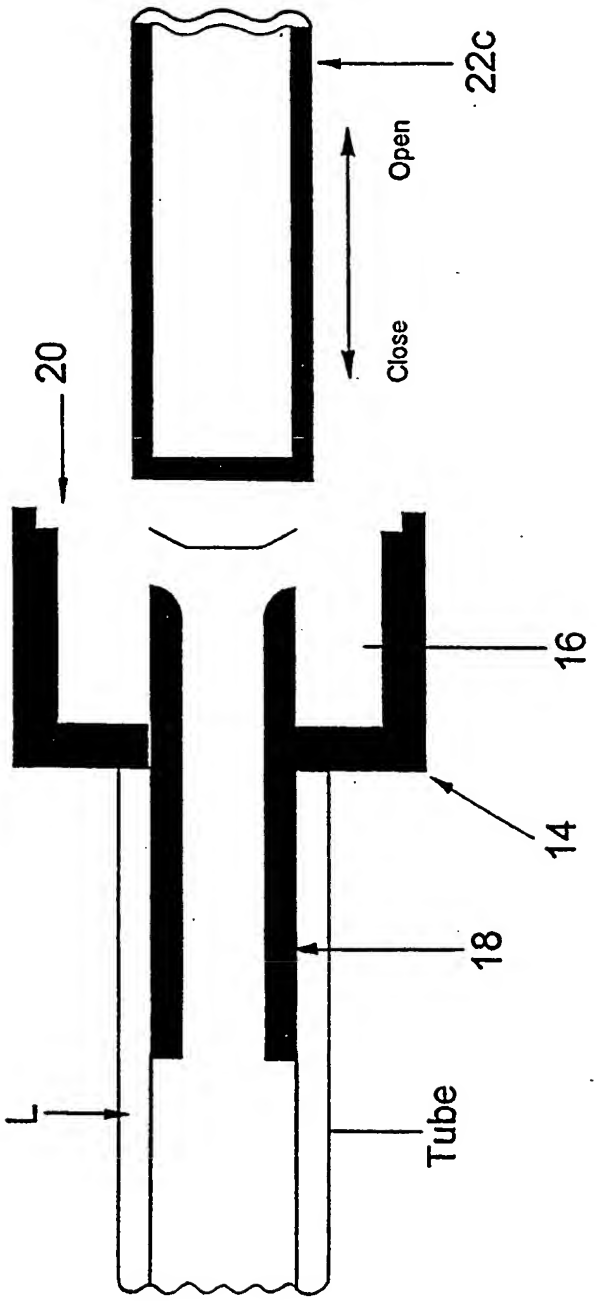

FIG. 2

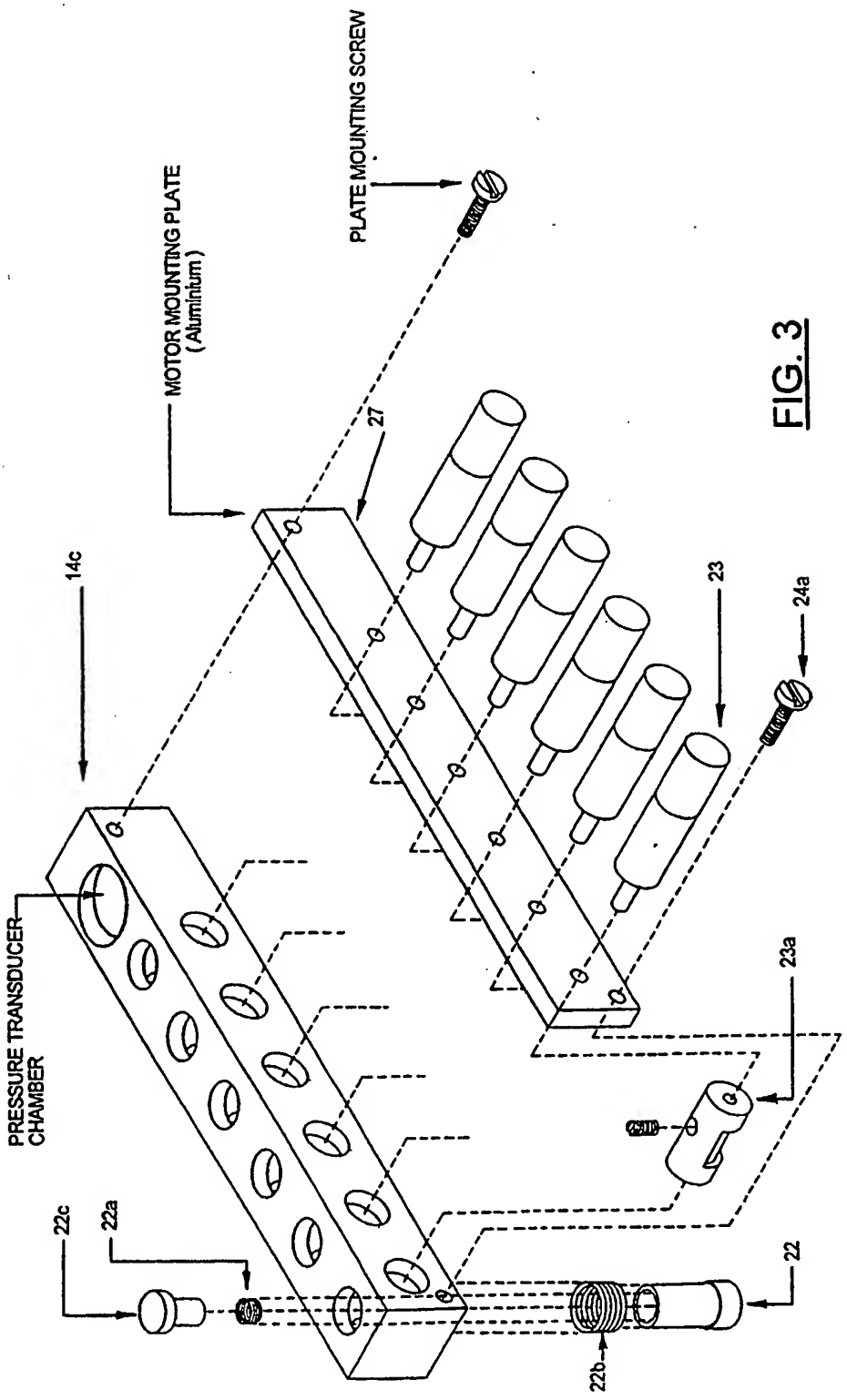
PLATE MOUNTING SCREW
MOTOR MOUNTING PLATE (Aluminium)
27
14c
23
24a
PRESSURE TRANSDUCER CHAMBER
23a
22c
22a
22
22b

FIG. 3

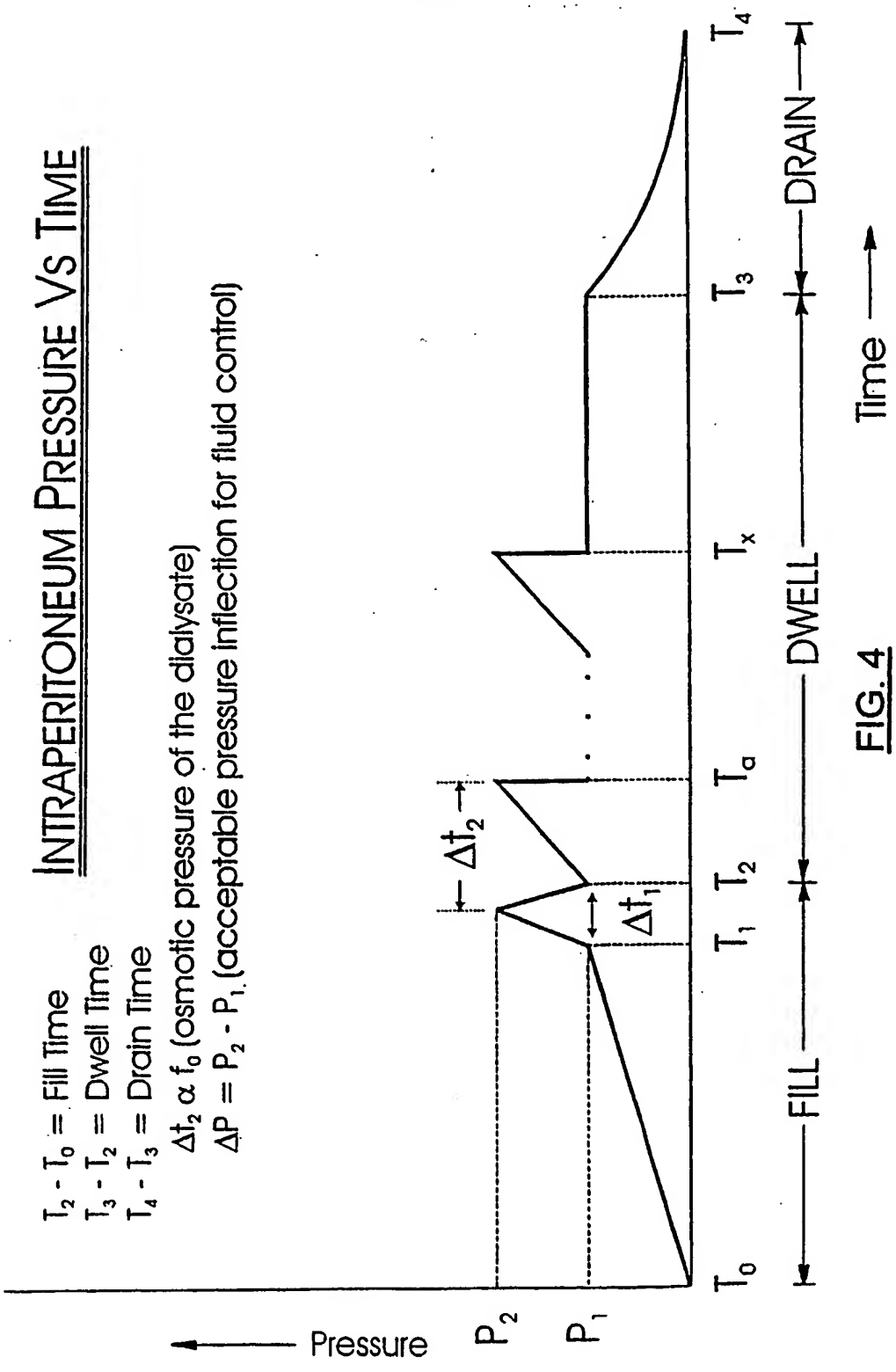
INTRAPERITONEUM PRESSURE VS TIME
$T_2 - T_0$ = Fill Time
$T_3 - T_2$ = Dwell Time
$T_4 - T_3$ = Drain Time
$\Delta t_2 \alpha f_0$ (osmotic pressure of the dialysate)
$\Delta P = P_2 - P_1$ (acceptable pressure inflection for fluid control)
Pressure
P_2
P_1
T_0
T_1 T_2
T_a
T_x
T_3
T_4
Δt_1
Δt_2
FILL
DWELL
DRAIN
Time

FIG. 4

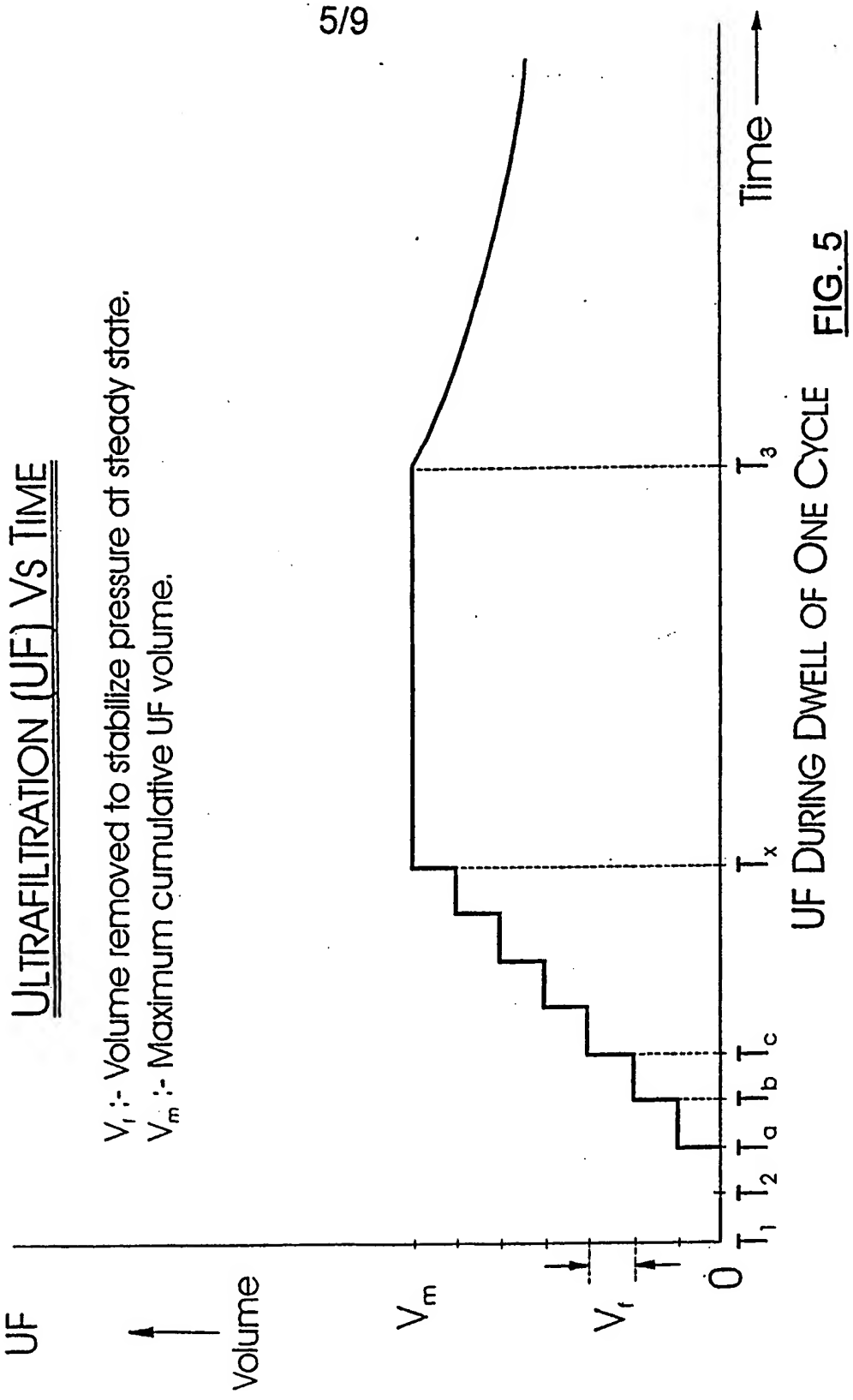
ULTRAFILTRATION (UF) VS TIME
V_r :- Volume removed to stabilize pressure at steady state.
V_m :- Maximum cumulative UF volume.
UF
Volume
V_m
V_r
0
T_1 T_2 T_a T_b T_c
T_x
T_3
Time
UF DURING DWELL OF ONE CYCLE

FIG. 5

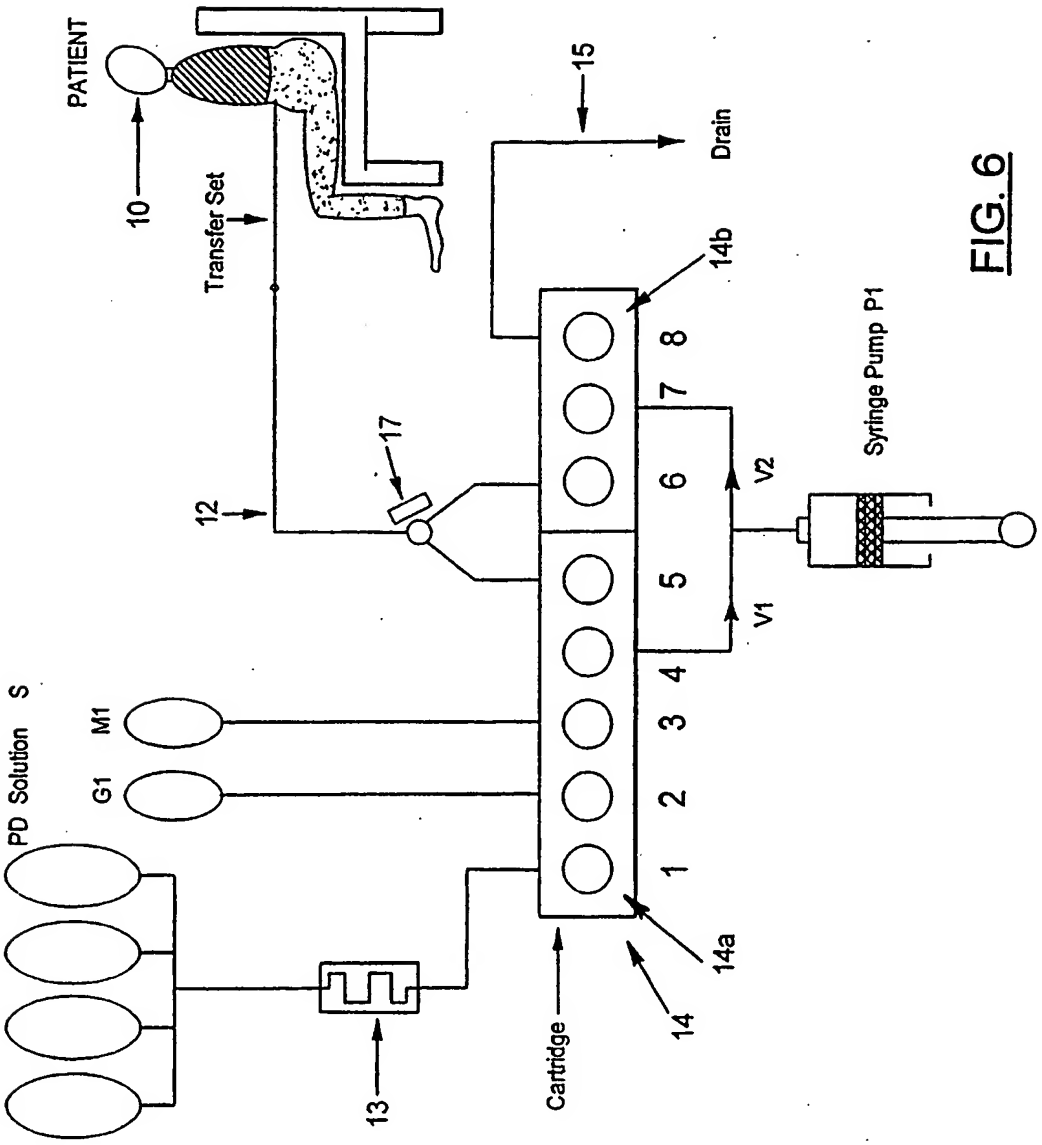
PATIENT
10
Transfer Set
12
15
Drain
14b
17
8
7
6
5
4
3
2
1
V2
V1
Syringe Pump P1
S
PD Solution
M1
G1
13
Cartridge
14a
14

FIG. 6

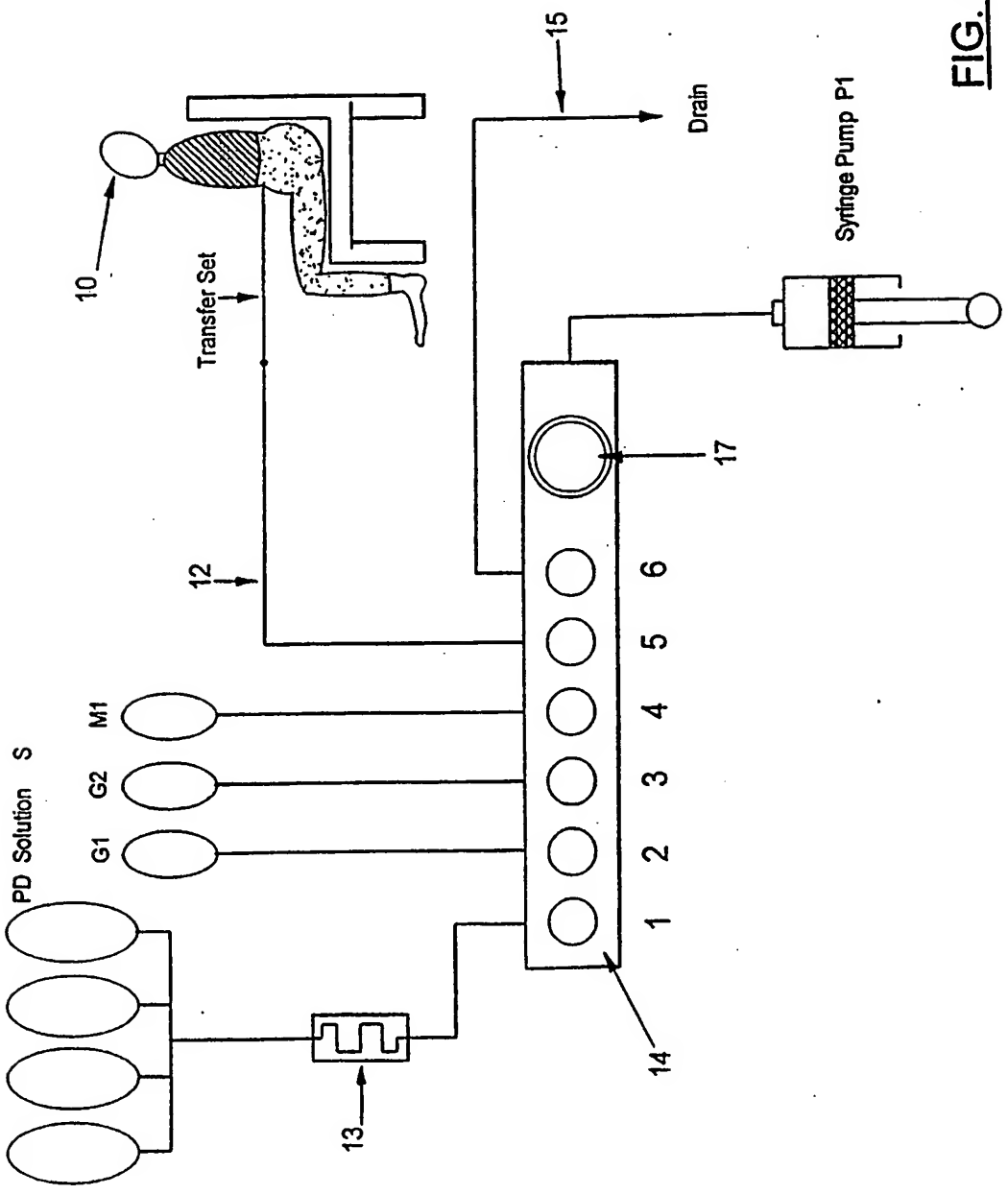
10
Transfer Set
12
15
Drain
Syringe Pump P1
17
1 2 3 4 5 6
14
13
PD Solution S
G1
G2
M1

FIG. 7

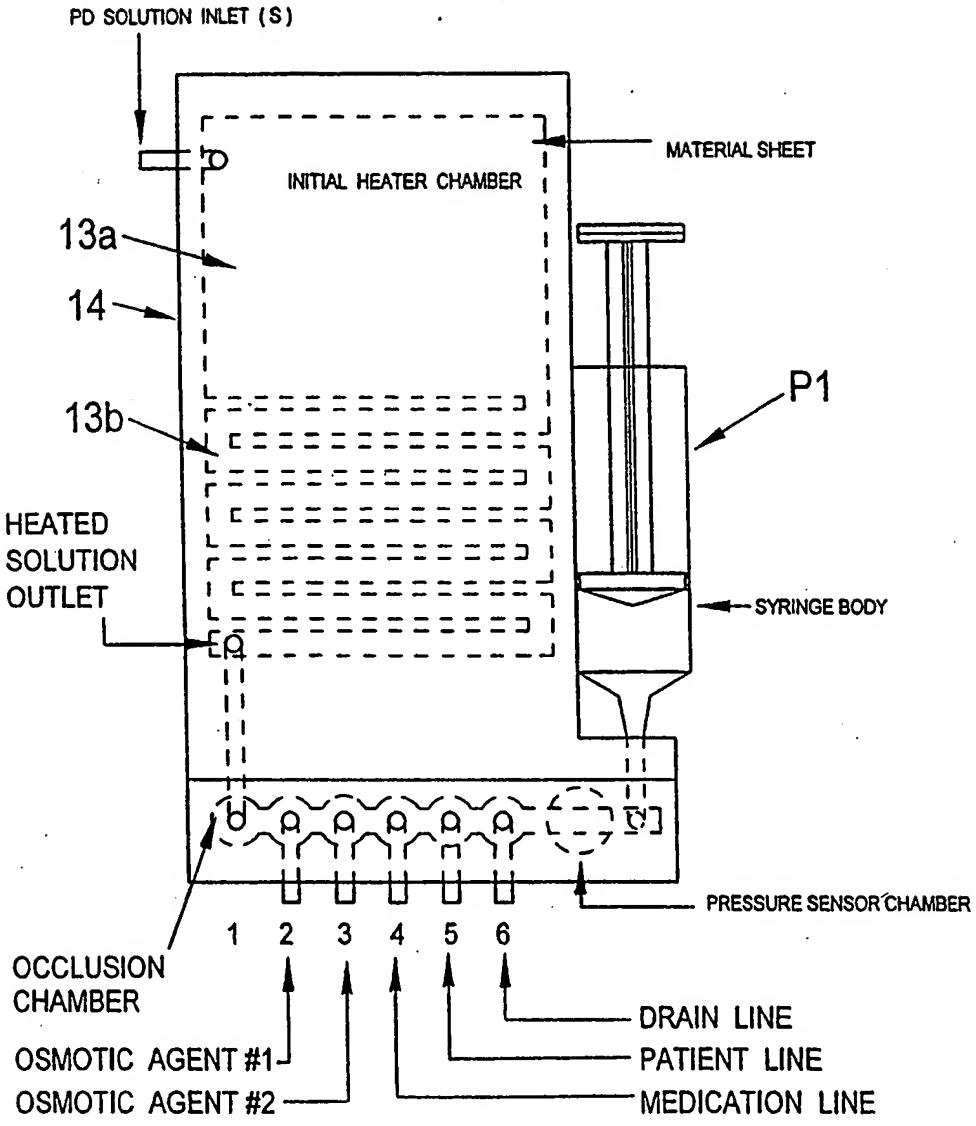
PD SOLUTION INLET (S)
MATERIAL SHEET
INITIAL HEATER CHAMBER
13a
14
13b
P1
HEATED SOLUTION OUTLET
SYRINGE BODY
PRESSURE SENSOR CHAMBER
1 2 3 4 5 6
OCCLUSION CHAMBER
DRAIN LINE
PATIENT LINE
MEDICATION LINE
OSMOTIC AGENT #1
OSMOTIC AGENT #2

FIG. 8

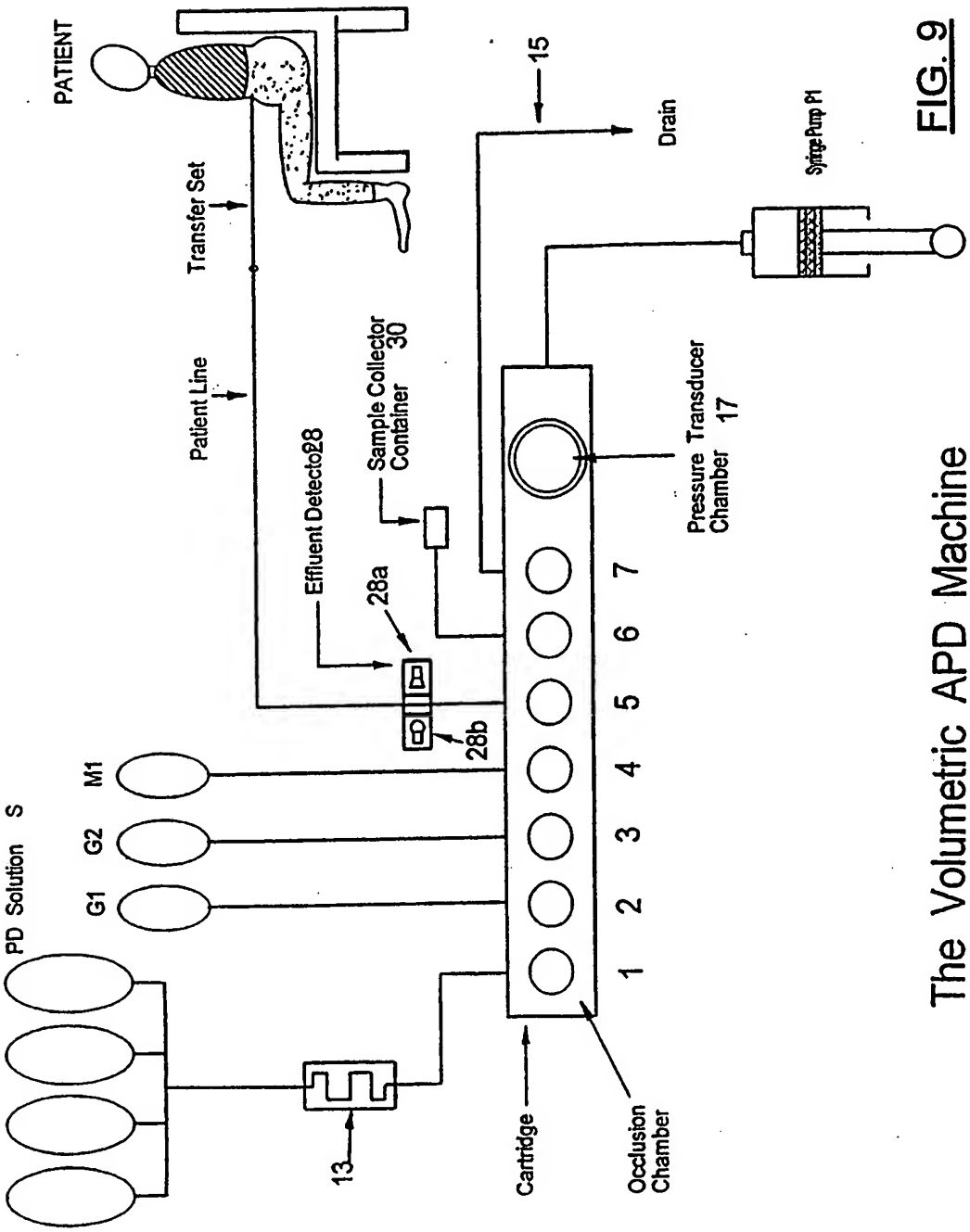

FIG. 9

The Volumetric APD Machine

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/CA 98/00722

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/16 A61M1/28

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61J

Documentation searched other than minimumdocumentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 19 64 735 A (HAUNI-WERKE KÖRBER & CO KG) 8 July 1971 see page 32, line 17 - page 33, line 28; claim 1; figures 9,10	1
Y	US 4 433 974 A (BISCHOF REINHARD) 28 February 1984 see abstract; figure 1 see column 1, line 46 - column 2, line 14 see column 2, line 29 - line 58	1
A	US 4 915 688 A (BISCHOF DECEASED REINHARD ET AL) 10 April 1990 see abstract; figure 1 see column 3, line 24 - column 4, line 32	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publicationdate of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of theinternational search	Date of mailing of the international search report
21 October 1998	30/10/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Zeinstra, H

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter. ...nal Application No
PCT/CA 98/00722

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category '	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 81 03180 A (BABB A;SCRIBNER B) 12 November 1981 see abstract; figures 1,4 see page 21, line 15 - page 22, line 10 see page 25, line 15 - page 26, line 16 see page 31, line 20 - line 23	1,7
A	DE 43 14 657 A (SEHRT FRIEDHELM ;MOCKENHAUPT ANDREAS (DE)) 10 November 1994 see abstract; figure 7 see column 5, line 44 - column 6, line 12	5
A	WO 95 35124 A (BAXTER INT) 28 December 1995 see abstract; figures 2,3,5 see page 10, line 3 - page 11, line 19	6

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 98/ 00722

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 8,9-16
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Intern ial Application No
PCT/CA 98/00722

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 1964735 A	08-07-1971	GB 1326236 A	08-08-1973
US 4433974 A	28-02-1984	NONE	
US 4915688 A	10-04-1990	NONE	
WO 8103180 A	12-11-1981	US 4326955 A	27-04-1982
		AU 7176881 A	26-11-1981
		CA 1166966 A	08-05-1984
		EP 0051659 A	19-05-1982
		GB 2084484 A,B	15-04-1982
		JP 57500565 T	01-04-1982
		SE 8200109 A	11-01-1982
		US 4399036 A	16-08-1983
DE 4314657 A	10-11-1994	NONE	
WO 9535124 A	28-12-1995	AU 688062 B	05-03-1998
		AU 2763195 A	15-01-1996
		CA 2167276 A	28-12-1995
		EP 0714312 A	05-06-1996
		JP 9501862 T	25-02-1997
		US 5641405 A	24-06-1997